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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,214	08/26/2003	Bradley Jascob	5074A-000001/COB	6133
27572	7590	10/31/2006	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			SOLANKI, PARIKHA	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,214	JASCOB ET AL.	
	Examiner	Art Unit	
	Parikha Solanki	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/26/03 and 1/09/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/26/03 and 6/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 14 June 2004 was filed after the mailing date of the original application on 26 August 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

2. Applicant's claim for the benefit of prior application 09/873,604, filed under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 27-50 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 10, 11, 12, 16, 19 and 25 of prior U.S. Patent No. 6,636,757. This is a double patenting rejection.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 30, 32, 47 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,636,757. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Regarding claims 30, 31, 47 and 49, the prior patent discloses that the transmitter coil includes a plurality of transmitter coils. The prior patent does not explicitly recite that the transmitter coil includes three sets of coils arranged orthogonal to one another. However, the use of three orthogonal coils in the transmitter component and three orthogonal coils in the receiver component of RF tracking systems is well known in the art, as it provides for specific tracking of an object's location to the precision of six degrees of freedom in a three-dimensional coordinate space. It would have been obvious to one of ordinary skill in the art at the time of invention to create the apparatus of the prior patent, further limiting the number of transmitter coils to three, and arranging such coils in an orthogonal orientation, in order to precisely track the three-dimensional location coordinates of a medical probe in the body during surgery.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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8. Claims 1, 2, 7 and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferre et al (US Patent No. 6,175,756), cited by Applicant in the Information Disclosure Statement. Ferre ('756) provides a method and system for monitoring the position of a medical instrument with respect to a patient's body, including a method of calibrating an imaging system under controlled conditions to account for the field distorting effects of ferromagnetic objects within the imaging field (Abstract, col. 10 lines 29-42).

Regarding claims 1 and 2, Ferre ('756) discloses the steps of positioning an electromagnetic navigation system in a working environment, positioning two calibration sensors at first and second calibration points, respectively, inducing an electromagnetic field in the working environment, and sensing the field strength at both sensors (col. 11 lines 5-21). Ferre ('756) specifies that the field generator comprises an array of three orthogonally disposed coils (col. 9 lines 35-37). Ferre ('765) further discloses that the measured values of the virtual sensor points are compared to the reference values of the virtual sensor points in order to determine the degree of difference between the calculated and known values, equivalent to the step of taking the effects of metallic distortion into account as claimed in the instant application (col. 11 lines 51-54).

Regarding claims 7 and 15, Ferre ('765) describes a surgical navigation procedure employing a flexible medical instrument with a sensor disposed at the tip, equivalent to the surgical probe claimed in the instant application (col. 13 lines 33-34).

Regarding claim 13, Ferre ('765) provides the step of comparing measured field values to stored field values acquired during calibration (col. 11 lines 50-53).

Regarding claim 14, Ferre ('765) states that the excitation of the transmitter coils is time division multiplexed (col. 9 line 46).

Regarding claim 16, Ferre ('765) discloses that the two calibration sensors are attached to headset, equivalent to the dynamic patient-affixed reference arc claimed in the instant application (col. 11 lines 5-10).

9. Claims 17-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al (US Patent No. 5,787,886), cited by Applicant in the Information Disclosure Statement.

Regarding claims 17-19, 21, 22 and 24, Kelly ('886) discloses a method for electromagnetically navigating a surgical stylus, which is equivalent to a probe, with a transmitter coil array, including the steps of referencing a calibration database, which is equivalent to a look-up table, to correct for metallic distortion, selecting an arbitrary guess point where the instrument is located, energizing the transmitter in a time-division multiplexed

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manner to generate an electromagnetic field adjacent to the metallic object, sensing the field with the stylus, interpolating the field strength at the guess point, calculating the difference between the acquired field strength data and the guess point, and subsequently refining the guess point (col. 7 lines 23-32, col. 9 lines 29-34, col. 10 lines 16-25, col. 11 lines 1-15, col. 19 lines 22-34). Kelly ('886) further discloses refining the guess point via a minimization process in order to reduce the error between the guess point and actual instrument location (col. 4 lines 16-20).

Regarding claim 20, Kelly ('886) discloses a linear interpolation method for calculating the field at an arbitrary point (col. 16 line 66 – col. 17 line 19).

Regarding claim 23, Kelly ('886) states that the metallic object causing electromagnetic field distortion may be an operating room table, a microscope, or an electrical monitoring device (col. 9 lines 12-18).

Regarding claim 26, Kelly ('886) shows that the surgical stylus is not connected to the transmitter, thus stylus receives the transmitted electromagnetic signal wirelessly (Fig. 2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferre ('756). Ferre ('756) teaches all features of the present invention as described above. Ferre ('756) does not specifically disclose that the calibration steps are repeated to collect approximately eight thousand calibration points. At the time of invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to collect approximately eight thousand calibration points in order to create a comprehensive calibration model while minimizing data distortion caused by outlier data points.

12. Claims 5, 6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferre ('756) in view of Kelly ('886).

Regarding claims 5 and 6, Ferre ('756) teaches all features of the present method as described above, with the exception of specifying the type of ferromagnetic object that causes

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the distortion. In the same field of endeavor, Kelly ('886) provides a method for calibrating a navigation system and correcting acquired navigation data for distortion effects caused by ferromagnetic objects, further specifying that the object may be a surgical table, operating microscope or electrical monitoring equipment (col. 9 lines 12-18). It would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Ferre ('756) during a surgical navigation procedure in which a surgical table, operating microscope, or similar equipment is present as a source of ferromagnetic distortion, in light of the teachings of Kelly ('886).

Regarding claims 8-12, Ferre ('756) teaches a method of calibrating an electromagnetic surgical navigation system, but is silent with respect to using the calibration data to correct the acquired instrument position data during surgery. Kelly ('886) teaches a method of correcting acquired navigation data including the steps of comparing stored calibration navigation data to the measured probe location data, and using the stored data to interpolate fields at an arbitrary point in space (col. 10 lines 1-6, col. 10 lines 16-25, col. 16 lines 51-53). Although Kelly ('886) does not refer to measuring and storing field strengths, that information is inherently described by position data. The method of Kelly ('886) includes computing the difference in data values between the arbitrary point and the acquired probe location data (col. 10 lines 16-25). Kelly ('886) provides steps for using that difference to refine the arbitrary point during a minimization process (col. 16 line 66 – col. 17 line 6). Kelly ('886) also teaches the step of minimizing the error between the arbitrary point and the probe location point (col. 10 lines 11-14). At the time of invention, it would have been obvious to one of ordinary skill in the art to modify the method of Ferre ('756) by including the method of Kelly ('866), in order to acquire accurate probe position data in the presence of field distortion inadvertently induced by eddy currents from other ferromagnetic objects in the operating room.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferre ('756) in view of Shapiro (US Patent No. 5,777,720). Ferre ('756) teaches all features of the present invention as described previously, with the exception of placing the calibration sensors with a robotic unit. In the same problem-solving area, Shapiro ('720) describes a method of calibrating a tracking display system, including the step of using a robot arrangement to place a calibration tracking sheet in the tracked field of view, to enhance the precision of positioning the sensor (col. 9 lines 13-16). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Ferre ('756) to further include the step of using a robot to

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position the calibration sensors in order to place the sensors with better precision, in view of the teachings of Shapiro ('720).

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly ('886) in view of Duffin (US Patent No. 5,752,976). Kelly ('886) teaches all features of the invention of claim 17 as described above, with the exception of specifying that the transmitter coil array is controlled via a wireless channel. In the same problem-solving field, Duffin ('976) provides a method for tracking an implantable medical device, employing a transmitter that is in wireless communication with a controller (Figure 2). The transmitter of Duffin ('976) provides the advantage of increased freedom of movement of the transmitter, so that its position within the imaging space is not limited to its relative distance from the controller. The problem of managing multiple wires and cables within an operating room in order to create a safer working environment is well-known in the art. In light of this motivation, it would have therefore been obvious to one of ordinary skill in the art at the time of invention to modify the method of Kelly ('886) to further control the transmitter via a wireless channel, in view of the teachings of Duffin ('976).

Conclusion


15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vemuri et al (An efficient motion estimator with application to medical image registration. *Medical Image Analysis*. 2(1): pp 79-98. 1998) teach a related spline minimization method for image registration in surgical navigation systems. Schneider et al (US Pat. No. 6,427,079) teach a related method of measuring position and orientation with magnetic fields in the presence of distortion-generating ferromagnetic objects.

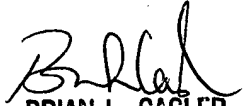
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Parikha Solanki
Examiner – Art Unit 3737


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